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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/765,668	01/27/2004	David B. Rozema	Mirus.042.02	9890

25032 7590 06/29/2005

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EXAMINER	
DUNSTON, JENNIFER ANN	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/765,668	ROZEMA ET AL.	
	Examiner	Art Unit	
	Jennifer Dunston	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 May 2005 and 13 June 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-8 and 12-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-8 and 12-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to the amendment, filed 5/26/2005, in which claims 5 and 12 were amended. Receipt is also acknowledged of an amendment, filed 6/13/2005, in which the specification was amended to correct a typographical error. Applicants' arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections and objections not reiterated in this action have been withdrawn. **This action is FINAL.**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

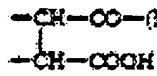
> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 5-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Maeda et al (US Patent No. 4,732,933; see the entire reference).

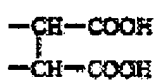
Maeda et al teach half-esterified styrene-maleic anhydride copolymers (SMA) covalently bound to the antitumor drug neocarzinostatin (NCS) (e.g. column 4, lines 4-10; column 3, lines 25-47). Maeda et al teach the following maleic acid units, wherein R is a monohydric alcohol

residue or a residue of monohydroxyalkyl ether of di- or trihydric alcohol (e.g. column 1, lines 20-46):

(1) maleic acid residue bonded to NCS

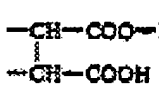


(2) maleic acid residue which is free or bound to NCS by non-covalent bonding



provided that the total amount of the above described maleic acid residues (1) and (2) is from an average content of 0.1 per molecule to 60 mol % of SMA, and

(3) half-esterified maleic acid residue



One such embodiment disclosed by Maeda et al is neocarzinostatin-half butyl-esterified styrene-maleic acid copolymer complex (SMANX) (e.g. Example 1).

Claims 5 and 12-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Tonge et al (US Patent No. 6,436,905; see the entire reference).

Tonge et al teach a composition comprising a synthetic amphipathic polymer, including both hydrophobic groups and anionic hydrophilic groups and acting as a lipid-solubilizing agent (e.g. column 3, lines 49-52). Tonge et al teach that especially suitable polymers may be formed as alternating copolymers of maleic acid (or the anhydride thereof) with styrene, indene or a C_{1-4} alkyl, e.g. methyl substituted styrene or indene, or with propyl (or isopropyl) or butyl vinyl ether (e.g. column 6, lines 27-31, 60-63). Tonge et al disclose examples of suitable polymers,

including Poly(maleic anhydride-styrene) (a random copolymer), Poly(maleic anhydride-propyl vinyl ether), and Poly(maleic anhydride-butyl vinyl ether) (e.g. column 6, lines 60-63).

Claims 12-13 and 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Calcaterra et al (US Patent No. 5,118,551; see the entire reference).

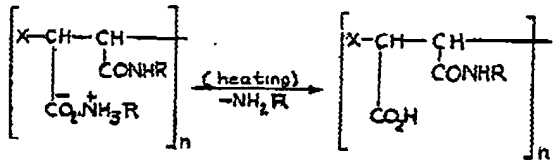
Calcaterra et al teach a copolymer consisting of hydrolyzed aromatic-containing vinyl ether maleic anhydride copolymer, a half ester of an aromatic-containing vinyl ether maleic anhydride copolymer, and mixtures thereof (e.g. column 1, lines 60-68). Embodiments disclosed by Clacaterra et al include an alternating copolymer prepared from phenyl vinyl ether and maleic anhydride, and the half isopropyl ester product of the copolymer (e.g. column 5, lines 1-7). Further, Calcaterra et al teach that the half isopropyl ester product of the alternating copolymer prepared from phenyl vinyl ether and maleic anhydride is preferred for resistance to hot coffee staining, and thus the isopropyl ester is a functional group (e.g. column 5, lines 1-13).

The polymers taught by Calcaterra et al necessarily read on the polymers of claims 12-13 and 15-17 because identical chemical structures will necessarily possess the characteristics of the claimed product.

Claims 12, 13, 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Smallman (GB 1241294, 1971; see the entire reference).

Smallman teaches amide-acid derivatives of alternating vinyl ether/maleic anhydride copolymers, described by the following reaction (e.g. page 1, lines 5-34):

The reaction may be represented as:—



where X represents the vinyl residue in the copolymer, R is hydrogen or alkyl, and n is an integer greater than 1.

Therefore, Smallman teaches alkyl vinyl ether-maleic anhydride alternating copolymers, wherein hydrophobic amides are covalently linked to anyhdride monomers in the polymer.

The polymers taught by Smallman necessarily read on the polymers of claims 12, 13, 15 and 16 because identical chemical structures will necessarily possess the characteristics of the claimed product.

Response to Arguments

Applicant's arguments filed 5/26/2005 have been fully considered but they are not persuasive. The response asserts that the amendments to the claims obviate the rejections in that the prior art does not teach that the claimed polymers are capable of lysing mammalian cell membranes at pH 6.5. In response to applicant's argument that the claimed polymers are capable of lysing mammalian cell membranes at pH 6.5, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). Absent any evidence to the contrary, one would necessarily

expect that the polymers taught by Maeda et al, Tonge et al, Calcaterra et al and Smallman et al are capable of lysing mammalian cell membranes at pH 6.5. For example, Tonge et al teach that styrene-maleic anhydride random polymer and vinyl ether-maleic anhydride-based alternating copolymers are capable of acting as lipid-solubilizing agents. Thus, one would necessarily expect that the polymers taught by Tonge et al would be capable of solubilizing the lipid bilayer of the plasma membrane of a mammalian cell, resulting in the lysis of the cell. Given the shared structural features of the polymers taught by each of the references applied under 35 U.S.C. § 102, one would expect that the polymers taught by the references are capable of lysing mammalian cell membranes at pH 6.5. For these reasons, the rejections are maintained.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dunston whose telephone number is 571-272-2916. The examiner can normally be reached on M-F, 9 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached at 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR, http://pair-

direct.uspto.gov) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jennifer Dunston
Examiner
Art Unit 1636

jad

TERRY MCKELVEY
PRIMARY EXAMINER